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Original Research Article

Intravenous Iron Therapy in Severe Anemia at 28-34 Weeks of Gestation and it's Feto-Maternal Outcome- A Prospective Study from A Developing Country

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Abstract:

Introduction: Iron deficiency anaemia (IDA) is the most common nutritional deficiency in pregnancy. Anemia results in poor pregnancy outcome and also affects fetal outcome. This study was undertaken to evaluate the response of intravenous iron given to pregnant women with severe IDA and their feto-maternal outcome.

Methodology: A prospective study was conducted in the department of Obstetrics & Gynaecology, at a tertiary care centre of Northern India. Fifty-two pregnant women with haemoglobin between 5-7 g% with diagnosed iron deficiency attending antenatal clinic were given intravenous iron complex Follow-up after 4 weeks was done and IDA specific blood profile was done at baseline and at follow-up. Feto-maternal outcomes were seen at delivery.

Results: The mean age of study population was 25.5 ± 3.96 yrs. Improvement at 4 week follow-up from baseline in hemoglobin (p value-0.001) and iron profiles (S. Iron, Total Iron Binding Capacity (TIBC), S. Ferritin) (p value -0.0001) were highly significant. On comparing the Hb levels at delivery after intravenous infusion at 28-34 weeks gestation, 17 patients were still below 8 gm%, whereas 35 were above 8 gm%. Distribution of IUGR, preterm labor and blood transfusion in postpartum period were statistically significant amongst both group (p value<0.05). Fetal outcomes were also evaluated amongst the 2 groups. Distribution of Preterm birth, birth weight and NICU admission was also statistically significant (p value<0.05).

Conclusion: The intravascular iron therapy definitely has a rapid increase in haemoglobin which can prevent the complications due to severe anaemia in pregnancy and blood transfusion can also be prevented, but iron stores are not replenished to the optimum level, so there is a need to give replacement therapy (by oral route) post transfusion for long term benefits. The rise of hemoglobin affects feto-maternal outcomes even in the last trimester.contrast agents. This is a first case report of AHCM portrayed by this ingenious technology.

Keywords: AMCH, IUGR, TIBC

Introduction

During pregnancy the most recurrent nutritional deficiency is anemia due to deficiency of Iron. During pregnancy, haemoglobin levels below 11 gm/dl is considered as anemic and when levels are below 7 gm/dl, it is categorised as severe anemia [1]. Such low haemoglobin levels is considered as a high-risk factor during pregnancy as it has been seen to be linked with frequent preterm deliveries and low birth weight with increased possibility of maternal mortality [2]. With appropriate and necessary interventions at appropriate time severe anemia can be rectified [1].

According to NFHS-5, the total prevalence of anemia in pregnant woman between ages 15-49 years is 52.2% 45.7% in Urban and 54.3 in Rural. This has increased from 50.4% in NFHS-4 data to 52.2%. [3,4]. Although recommendations to treat severe anemia where haemoglobin levels are between 5 gm/dl to 6.9 gm/dl, is intravenous iron infusion upto 34 weeks of pregnancy. Still, blood transfusion is the fancied treatment choice to correct severe anemia in later stage of pregnancy as it has an instant improvement in the haemoglobin levels. [5].

In necessitous settings, the accessibility and transfusion facilities are lacking. So, infusion of iron intravenously comes in handy and easily available at the low resource medical setups or Primary Health Centres (PHCs). [6] A speedy recovery of haemoglobin levels is necessary to prevent the bad outcomes of pregnancy rapid improvement in haemoglobin levels such that poor pregnancy outcomes are prevented.[7] Therefore, the objective in this was to evaluate the rise in haemoglobin levels in pregnant woman who suffer from severe anemia and compare the feto-maternal outcomes.

Material and Methods

It is a prospective study. All pregnant women between 18-35 years singleton pregnancy of 28-34 weeks gestation attending antenatal clinic in St. Stephens Hospital, Tis Hazari, in New Delhi, India for a period of 1 year was screened for anemia using hemoglobin estimation as criteria. Exclusion criteria were those who revealed parasitic infestation in stool examination, S. ferritin >15mcg/L.

Underlying diseases such as gestational diabetes mellitus, hypertension, any heart disease, gastric/peptic ulcer etc., with drug allergy to iron, previously diagnosed as thalassemia disease. History of coagulation defect or bleeding tendency and blood transfusion within 120days.

Those who consented to take part were included into the study after taking an informed consent. Finally, 52 severely anemic pregnant females were included in the study. For those patients enrolled, hemoglobin estimation was done using auto analyser method. After they were explained about the stratagem and the requirement to treat anaemia. All patients were given the first dose after admission to hospital and then followed up on an outpatient basis for rest of the doses. All the necessary investigations for anaemia were sent as mentioned in the proforma. The details of the patients were entered using a pre designed semi structured tool.

Deworming of all the patients was done with tablet mebendazole (Tab. Mebex) 100mg twice a day for 3days. Oral therapy of iron was discontinued and only 5 mg of folic acid once daily dosing was introduced.

Phase I: Calculated dose of intravenous iron was given as infusion over 15-20 min with maximum of 200 mg per day every alternate day three days a week. Only oral consumption of folic acid was prescribed during this period. The treatment was ceased in case of occurance

of any significant side effects and the patient was treated symptomatically.

Phase II: Post intravenous therapy for 1 week at follow up at 2weeks and 4 weeks of last dose of intravenous iron, Hemoglobin and other blood investigations were repeated. Oral Iron was continued after follow-up as required daily during pregnancy.

Complete blood count was evaluated using ETDA samples from patient analysed on Beckman Coulter LH 780, haematology analyser. The parameters analysed were haemoglobin, Mean Corpuscular Volume (MCV), Mean Corpuscular Haemoglobin (MCH), Mean Corpuscular Haemoglobin Concentration (MCHC), Red cell Distribution Width (RDW). The normal values for MCV are 82-92fl, for MCH are 27-32pg , for MCHC are 32-36g/dl & for RDW are 11.5-13.5%. Serum iron & Total Iron Binding Capacity (TIBC) were interpreted using Hitachi 917 biochemistry analyser. The normal values for serum iron are 38g/dl & for TIBC are 228-428g/dl. Serum ferritin was analysed by chemiluminsence using Immulite analyser. The normal values for serum ferritin are 6-159ng/ml. Patients were followed up for feto-maternal outcome till delivery.

Statistical analysis: The statistical analysis was done using SPSS version 24.0. Repeated measure analysis was done followed by post-hoc comparison by Benferroni method to see the trend of parameters with time. Confidence intervals (95%) of various proportions were also calculated. P< 0.05 was taken as significant.

Results

The mean maternal age of study participants was 25.5 ± 3.96 years. Most women were below 25 years of age (59.62%). 20 (38.38%) were primigravida whereas only 10 (19.23%) were >3 gravida**. (Fig. 1**) The mean BMI was 21.45 ± 2.29 kg/m^2 and mean baseline Hb was 6.24 ± 0.56 gm/dl. Most were unbooked ANC (57.69%). Mean gestational age at delivery was 36.78±1.87 weeks. Most patients delivered vaginally (65.38%). **(Table 1)**

Mean Baseline HB, S. Iron, Total Iron Binding Capacity (TIBC), S. Ferritin, Reticulocyte count, Red cell Distribution Width (RDW), Mean Corpuscular Volume (MCV), Mean Corpuscular Hemoglobin (MCH), Mean Corpuscular Hemoglobin Concentration (MCHC) levels were all below the normal values. Significant improvement was seen after intravenous iron therapy when followed-up after 2 and 4 weeks from the last dose. Improvement in hemoglobin and iron profiles were highly significant (p value <0.0001**). (Table 2)**

Most common Obstetric complication seen in the study participants was Intra Uterine Growth Restriction (N=24 (46.2%)), followed by Preterm labor in 32.6% (N=22) and pre-eclampsia in 17.3% (N=9). Out of 52 deliveries of the mothers who received iron therapy, only 22 (42.3%) were preterm deliveries and 42 (80.8%) newborns were low birth weight, whereas only 7 (13.5%) were of normal birth weight. Only 3 (5.7%) were very low birth weight babies. **(Fig. 2)**

On comparing the Hb levels at delivery after intravenous infusion at 28-34 weeks gestation, 17 patients were still below 8 gm%, whereas 35 were above 8 gm%. Distribution of IUGR, preterm labor and blood transfusion in postpartum period were statistically significant amongst both group (p value<0.05). **(Table 3)** Fetal outcomes were also evaluated amongst the 2 groups. Distribution of Preterm birth, birth weight and NICU admission was also statistically significant (p value<0.05). **(Table 4)**

Only 3 major side effects were seen in our study. Half of the patients had no side effect (50%). Out of the other half, 15 (28.8%) had myalgia, 8 (15.3%) had episode of fever and 3 (5.7%) had hypotension. (**Table 5)**

Table 1: Baseline data of study participants

Variables		N =52(%); Mean (±SD) Number (%)
Mean Maternal Age (years)		25.5 ± 3.96
Maternal Age Category	**≤25 years**	31 (59.62%)
	>25 years	21 (40.38%)
Gravidity	**Primi**	20 (38.46%)
	>1-3	22 (42.31%)
	>3	10 (19.23%)
Mean BMI (kg/m^2)		21.45 ± 2.29
Mean Hb (gm%)		6.24 ± 0.56
ANC	**Booked**	21 (40.38%)
	Unbooked	30 (57.69%)
Mean Gestational Age at Delivery (weeks)		36.78±1.87 (weeks)
Mean Time since last dose intravenous Iron Therapy (days)		5.78 ±2.14 (days)
Mode of Delivery	**Normal vaginal Delivery**	34 (65.38%)
	Caesarean	18 (34.62%)

Table 2: Descriptive statistics of blood indices for anaemia at baseline and at 2 weeks and 4 weeks post iron therapy.

Variables	Baseline	2-week post Intervention	4-week post Intervention	P value
Mean Hb (gm %)	6.24 ± 0.56	7.89 ± 0.60	8.53 ± 0.51	**0.001**
Serum Iron (µd/gl)	30.72 ± 5.00	42.94 ± 8.42	62.42 ± 9.5	**0.0001**
TIBC (µd/gl)	397.2 ± 37.7	358.8 ± 11.8	309.5 ± 8.6	**0.0001**
Serum Ferritin (µd/gl)	7.33 ± 1.05	17.64 ± 9.3	42.17 ± 23.22	**0.0001**
Reticulocyte count (%)	1.50 ± 0.60	4.6 ± 0.8	5.5 ± 1.8	**0.032**
RDW (%)	20.3 ± 2.48	18.8 ± 0.78	14.77 ± 0.91	**0.01**
Mean Corpuscular Volume (MCV) (fl)	72.6 ± 4.07	76 ± 4.5	87.5 ± 4.76	**0.041**
Mean Corpuscular Haemoglobin (MCH) (pg)	22.12 ± 1.67	27.12 ± 2.14	31.05 ± 1.96	**0.002**
Mean Corpuscular Haemoglobin Concentration (MCHC) (g/dl)	27.34 ± 1.9	31 ± 2.3	43.34 ± 2.6	**0.0001**

Table 3: Distribution of patients on the basis of maternal haemoglobin at delivery (after intravenous iron therapy at 28-34 weeks gestation) and Obstetric Complications

Obstetrics Complications*	Hb (gm%)		P value
	<8 gm% (N=17) Number (%)	**≥8 gm% (N=35) Number (%)**	
Pre-eclampsia	5(29.41%)	4 (11.43%)	0.852
Intra Uterine Growth Restriction	15 (88.24%)	9 (25.71%)	**0.002**
Preterm Labor	13 (76.47%)	9 (25.71%)	**0.043**
Preterm Premature rupture of membranes	2 (11.76%)	1 (2.86%)	0.098
Gestational Diabetes Mellitus	1 (5.88%)	1 (2.86%)	0.747
Ante-partum Hemorrhage	1 (5.88%)	0 (0.00%)	0.845
Post Partum haemorrhage	3 (17.65%)	1 (2.86%)	0.056
Blood transfusion in post partum	7(41.18%)	2 (5.71%)	**0.013**
	**Multiple Answers*		

Table 4: Distribution on the basis of maternal heamoglobin at delivery (after intravenous iron therapy at 28-34 weeks gestation) and Fetal Complications

Fetal Outcomes		Hb (gm%)		P Value
		<8 gm% (N=17) Number (%)	≥8 gm% (N=35) Number (%)	
Preterm birth	Yes	13 (76.47%)	9 (25.71%)	0.001
	No	4 (23.53%)	26 (74.29%)	
Birth weight	Normal	0 (0.00%)	7 (20.00%)	0.028
	Low birth weight	14 (82.35%)	28 (80.00%)	
	Very low birth weight	3 (17.65%)	0 (0.00%)	
NICU Admission		8 (47.06%)	2 (5.71%)	0.003

Table 5: Distribution of study participants on the basis of side effects seen during administering iron therapy (N=52)

Minor Side Effects	No. of Patients (Percentage)
No Side effects	26 (50%)
Myalgia	15 (28.85%)
Fever	8 (15.38%)
Hypotension	3 (5.77%)

Fig. 1: Distribution of study participants on the basis of gravidity

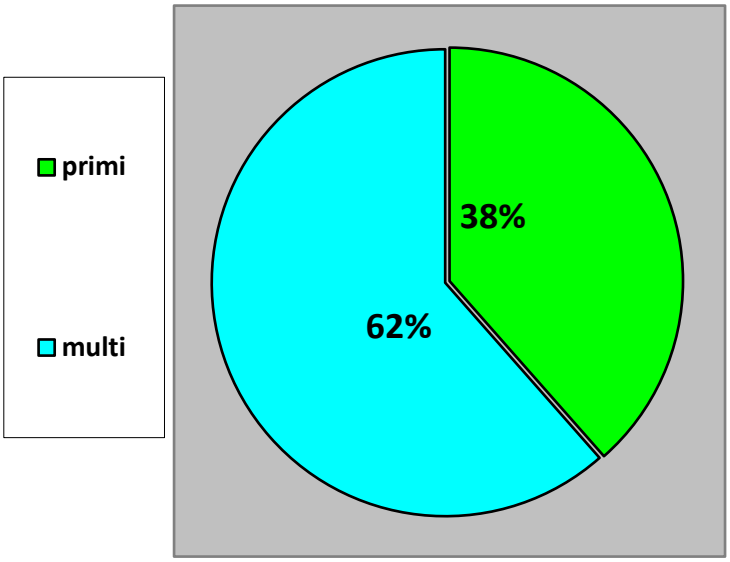
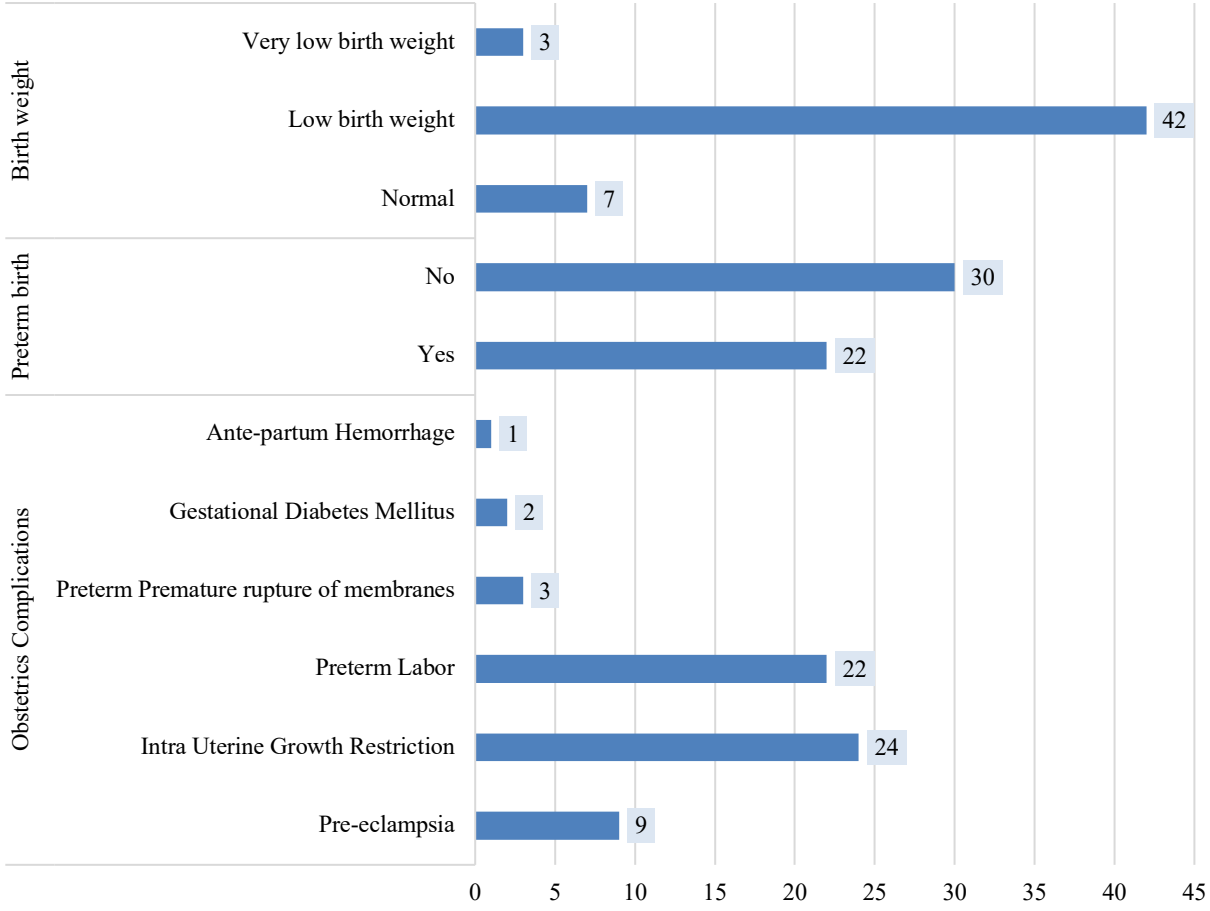


Fig. 2: Distribution of study participants on the basis of Feto-maternal complication



Discussion

The prevalence in developed countries is 14%, in developing countries 51%, and in India, it varies from 65% to 75%. [8,9] Most of the reported anaemia mothers are in third trimester of pregnancy, since the iron demand reaches 6.6 mg/day in this period as there is disproportionate increase in plasma volume and red cell mass causes hemodilution and it lowers the haemoglobin level. Anemia during pregnancy is commonly associated with poor pregnancy outcome and may lead to complication of mother like Prolonged labour and increase incidence of postpartum haemorrhage and also lead to preterm birth, low birth weight and small-for-gestational age babies and prematurity. [10-12]

Low haemoglobin levels in pregnancy has been seen to be associated with poor feto-maternal outcomes. [13,14] Oral iron has many side effects and is tolerated poorly, although it is the standard drug for the treatment of IDA in pregnancy. [4] Quick correction of Hb level is possible by intravenous administration of iron. Studies have report the safe and effective use of intravenous iron pregnant women who were anemic and who did not tolerate oral iron. [15,16]

There is a difference in requirement of elemental iron for prophylaxis in pregnancy between eastern and the western world. With

sufficient iron stores western pregnant woman need 30-40 mg elemental iron per day [17,18], whereas Indian women are deficient and they need around 100 mg elemental iron per day for prophylaxis. For treating anemia in pregnancy, recommended dose is 200 mg elemental iron everyday. [18] Intravenous iron has an upper edge to orally administered iron with respect to faster rise in Hb and quick replenishment of body iron stores. It also reduces the need for transfusion of blood and can be easily administered on outpatient basis.[19]

The definitive solution is to eradicate iron deficiency during or even before pregnancy.[19] The rising prevalence of IDA in pregnancy, thirty years after the initiation of the IFA program is an indictment of the failure of this program, and the urgent need to explore alternative approaches.

The mean age of patients enrolled in our study was 25.5 ± 3.96 yrs with a mean baseline Hb of 6.24 ± 0.56 gm/dl. This was lower than another similar study from India which has a baseline Hb of enrolled participants of 7.63 ± 0.61 gm/dl with a mean age of women was 27.8 ± 3.9 (range 21-34) yr. [19] The mean rise in haemoglobin in our study was 2.29 ± 0.105 gm/dl similarly another study from the same region had an increase in haemoglobin from 7.63 ± 0.61 gm/dl to 9.90 ± 0.80 gm/dl in 4 weeks follow-up. [19]

In a study to compare the clinical efficacy and safety of intravenous iron sucrose with intramuscular iron sorbitol citrate, it was found that rise of Hb was more in intravenous group. [20] These studies emphasized the superiority of iv iron therapy to intramuscular therapy in terms of rise of Hb and also safety profile. [19,20]

Similar to ours study, another study from northern India showed Mean (standard deviation) Hb increased from 7.85 g/dL (0.80) at baseline, to 9.62 g/dL (1.30) at endline, with a mean increase of 1.76 g/dL (95% confidence interval 1.67, 1.85). The mean increase in Hb-level for pregnant women who had severe and moderate anemia at baseline was 2.54 g/dL and 1.65 g/dL, respectively. [21]

The mean rise in S. Ferritin in our study was 34.84 (18.2-51.48) which was significant but still not appropriate and would still require oral iron supplementation for maintenance. Jacob OM et al, (2020) found the mean change in the Hb and serum ferritin level 4 weeks after the last dose of IV iron sucrose was an increase of 2.5 (2.1–3.0) g/dL ($P < 0.001$) and 63.0 (44.7–81.3) ng/mL ($P < 0.001$), respectively. Reason for the discordance could be the including moderately anemic in their study. [22]

As compared to previous studies, ferritin levels in our study women showed a lesser increase. The reason can be due to severely depleted iron stores in Indian women. [19,20,23]

Major disadvantages of intravenous treatments are it's expensive, need for hospitalization or an outpatient day-care setting, and the invasive nature of the procedure. However, it may be considered an alternative to blood transfusion for safe motherhood & delivery in the treatment of pregnant women with severe iron deficiency anaemia during the third trimester. [24]

Even after intravenous therapy, the patients when followed up till delivery did not have adequate hemoglobin levels. The feto maternal outcome was compared between those whose hemoglobin at delivery was less than or more than 8 gm/dl. IUGR, preterm labour and birth, low birth weight were the most commonly significant feto-maternal outcome.

An Indian study concluded that neonatal complications, like premature birth, NICU admission, perinatal death, low birth weight etc were significantly higher in neonates of mothers who were severely anemic and maternal complications were also higher in this group where preeclampsia and IUGR were the most common complication. [25] Another study by Savaliya K et al, studied only

multigravida severely anemic women and found that preterm labor, PPH and low birth weight were the most commonly observed feto-maternal complications. Intrauterine death was also seen in 4(10.25%) severely anemic women. [26]

Many studies have shown similar feto-maternal outcomes [12,25,26] but our study also compares the outcome after intravenous therapy, comparing those with Hb below and above 8 gm/dl at delivery. Limitiations of our study was lack of control group (non anemic pregnant women) and its non-randomisation. Large randomized controlled trials are required to compare the efficacy and safety of intravenous iron and comparison with non anemic women.

In conclusion, our results showed that rise of hemoglobin affects feto-maternal outcomes even in the last trimester. Intravascular iron therapy definitely has an increase in haemoglobin which can prevent the complications due to severe anaemia in pregnancy and blood transfusion can also be prevented, but iron stores are not replenished to the optimum level, so there is a need to give replacement therapy (by oral route) post transfusion for long term benefits.

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